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EXAMINER	
SASAN, ARADHANA	

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1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/758,233	BERTELSEN ET AL.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *68,70-72,75-80,82,83,85-96,108,109,111 and 115-126* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *68,70-72,75-80,82,83,85-96,108,109,111 and 115-126* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The remarks and amendments filed on 04/16/09 are acknowledged.

2. New claims 123-126 were added.

3. Claims 68, 70-72, 75-80, 82-83, 85-96, 108-109, 111 and 115-126 are included in the prosecution.

Response to Arguments

Rejection of claims under 35 USC § 103(a)

4. Applicant's arguments, see Page 9, filed 04/16/09, with respect to the following rejections under35 U.S.C. 103(a) have been fully considered but are not persuasive.

- Rejection of claims 68, 70-72, 75-80, 82-83, 85-86, 91-92, 95-96 and 108-111 under 35 U.S.C. 103(a) as being unpatentable over Nemoto et al. (JP 03-240729) in view of Bhardwaj et al. (US 5,578,316) and Melia et al. (Aliment. Pharmacol. Therap. (1989) 3, 513-525) .
- Rejection of claims 87-90, 93-94 and 115-120 under 35 U.S.C. 103(a) as being unpatentable over Nemoto et al. (JP 03-240729) in view of Bhardwaj et al. (US 5,578,316), Melia et al. (Aliment. Pharmacol. Therap. (1989) 3, 513-525) and Penkler et al. (US 5,854,226).
- Rejection of claims 121-122 under 35 U.S.C. 103(a) as being unpatentable over Nemoto et al. (JP 03-240729) in view of Bhardwaj et al. (US 5,578,316), Melia et al. (Aliment. Pharmacol. Therap. (1989) 3, 513-525) and Olinger et al. (US 5,651,988).

Applicant argues that Melia does not teach compositions of particulate granules of a specific size and that Melia teaches particulate active pharmaceutical ingredient (API), i.e., drug of a specific size. Applicant argues that Melia is concerned with API particle size, not with granule particle size. Applicant argues that there is no teaching or suggestion regarding how granulation should be performed, or even if it should be performed as undesirable drug transformations can occur.

This is not persuasive because with respect to combining references (Nemoto, Bhardwaj and Melia), the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Melia is used as a supporting reference that provides the relationship between reducing particle size, increasing dissolution rate and improving bioavailability. Melia refers to particle size of the API. However, one of ordinary skill in the art would know that reducing the particle size of granules of an API would consequently lead to increasing dissolution rate because of the increased surface area of the reduced particle size API granules. Moreover, the secondary reference (Bhardwaj) teaches that the "core particles which are to be coated can be composed of pure granular drug material **or** drug granules prepared in the conventional manner employing appropriate binding

agents" (Col. 2, lines 16-20). Therefore, the references are properly combined and render the instant claim limitations obvious.

Applicant argues that there can be no teaching or motivation to provide the formulation of Nemoto as a chewable tablet, that the formulation of Nemoto would be provided as a capsule or tablet for disintegration in the stomach that need not be administered in a large amount.

This is not persuasive because the teaching of Bhardwaj is not limited to a chewable tablet. The composition of Bhardwaj is directed to a composition for oral administration and one of ordinary skill in the art would take the teaching as a whole as referring to an orally administrable composition (Bhardwaj, Col. 6, lines 11-24, claim 1). One of ordinary skill in the art would not be limited to the chewable tablet embodiment of Bhardwaj and therefore, when combined with Nemoto would not require modification of Nemoto to be a chewable composition.

Applicant argues that one of skill in the art would not recognize particle size as a "result effective variable" to solve any problem alleged by the Office Action to be provided by the teachings of Nemoto. Applicant argues that no reference has been provided by the examiner to demonstrate that one of skill in the art would recognize particle size as a "result effective variable" for improved dissolution.

This is not persuasive because the teachings of Melia (reducing particle size leads to increased dissolution rate and improved bioavailability), Klioze (rapidly disintegrating tablets with granules that are between 149μm and 840μm), and Bhardwaj (composition with granules between 200 and 400 microns) demonstrate that one of

ordinary skill in the art would have recognized that particle size is a result effective variable for increasing dissolution.

Applicant argues that the alleged teachings of desirable hardness of tablets by Olinger provide no expectation that modification of the granule size would provide a tablet of the desired hardness.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case Olinger is combined with Nemoto, Bhardwaj and Melia to render the limitations of claims 121-122 obvious.

Therefore, the rejections are maintained.

5. Applicant argues that the newly added claims 123-126 cannot be obvious in view of the cited art. New grounds of rejections for new claims 123-124 based on Nemoto, Bhardwaj, Melia and Klioze follow. Since this new ground of rejection was necessitated by Applicant's amendment, this action is made FINAL.

6. Regarding newly added claims 125-126, the limitation of the granulate is rendered obvious by the teachings of Nemoto. Therefore, claims 125-126 are included in the rejection, as necessitated by Applicant's amendment.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 68, 70-72, 75-80, 82-83, 85-86, 91-92, 95-96, 108-111 remain rejected and new claims 125-126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nemoto et al. (JP 03-240729) in view of Bhardwaj et al. (US 5,578,316) and Melia et al. (Aliment. Pharmacol. Therap. (1989) 3, 513-525).

The claimed invention is a quick release pharmaceutical composition for oral administration comprising a therapeutically and/or prophylactically active substance which has a solubility of at the most 0.1% w/v in 0.1 N hydrochloric acid at room temperature, the composition being in the form of a particulate composition or being based on a particulate composition, wherein either the particles of the particulate composition used in the manufacture of the composition have a mean particle size of the most 250 micrometers, or at least 50% w/w of the particles of the particulate composition used in the manufacture of the composition pass through a 180 micrometer sieve; wherein the quick release pharmaceutical composition contains the active substance in contact with an alkaline substance; and the composition, when tested in accordance with the dissolution method I defined herein employing 0.07N hydrochloric acid as dissolution medium, releases at least 50% w/w of the active substance within the first 20 minutes of the test.

Nemoto teaches "an oral solid preparation containing one or more types of antacids that accelerates the absorption of oxicam antiinflammatory drugs" (Page 1, claim 1). Sodium hydrogen carbonate is disclosed as the antacid (Page 1, claim 3). The

antacid "accelerates the absorption of oxicam antiinflammatory drugs" (Page 2). Granules of the antacid and oxicam antiinflammatory drug are disclosed (Page 3). The granules are formed in a mixture of alcohol and purified water (Page 4). Capsules and tablets are manufactured by adding a lubricant to the granules (Page 4). The solubility of the prepared tablets in artificial gastric juice was greater than 50% within 20 minutes of the test (Page 9, Table 3).

Nemoto does not expressly teach a mean particle size of the most 250 micrometers of the granules.

Bhardwaj et al. (US 5,578,316) teach a pharmaceutical granule composition for oral administration where the final particle size of the granule is from about 200 to about 400 microns (Col. 6, claim 1, lines 11-24). A chewable tablet containing the pharmaceutical granule composition is also disclosed (Col. 6, claim 5, lines 35-37).

Melia et al. (Aliment. Pharmacol. Therap. (1989) 3, 513-525) teach that drug particle size is a characteristic that influences dissolution from tablets and capsules (Page 515). Melia teaches that "increasing the available surface area by reducing the particle size can often markedly improve dissolution rates and lead to dramatic improvements in bioavailability" (Page 515, 1st full paragraph, under the heading "Drug particle size").

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make an oral solid preparation containing one or more types of antacids that accelerates the absorption of oxicam antiinflammatory drugs, as suggested by Nemoto, combine it with the pharmaceutical granule composition for oral

administration where the final particle size of the granule is from about 200 to about 400 microns, as taught by Bhardwaj, and produce the instant invention.

One of ordinary skill in the art would do this because an orally administrable tablet composition that releases the active rapidly (a chewable tablet that disintegrates in the mouth will rapidly release the granules that are in the tablet) produced by using a granule composition where the final particle size of the granule is from about 200 to about 400 microns is known in the art, as evidenced by Bhardwaj. The particle size range of the granule taught by Bhardwaj renders the instant claims with the limitation of the mean particle size of the particles of the particulate composition at the most 250μm obvious to one of ordinary skill in the art. Furthermore, one of ordinary skill in the art would know that by modifying the drug particle size, i.e. by reducing the drug particle size, the surface area is increased and consequently, the dissolution rate is increased, which further leads to improved bioavailability, as evidenced by Melia.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claims 68 and 70, the limitation of the active substance would have been obvious over the oxicams taught by Nemoto (Page 1, claim 1). The limitation of the active substance in contact with the alkaline substance and the limitation of a particulate composition would have been obvious over the granules of antacid and

oxicam disclosed by Nemoto (Page 3). The limitation of the dissolution method employing 0.07N HCl acid as dissolution medium would have been obvious over the artificial gastric juice (with an acidic pH) taught by Nemoto (Page 9, Table 3). The limitation of the mean particle size of at the most 250 micrometers would have been obvious over the granules of antacid and oxicam disclosed by Nemoto (Page 3) in view of the final particle size of granules from about 200 to about 400 microns, as taught by Bhardwaj (Col. 6, claim 1, lines 11-24).

Regarding instant claim 71, the limitation of at least 55% w/w release would have been obvious over the solubility of preparations 3-9 as disclosed by Nemoto (Page 9, Table 3).

Regarding instant claim 72, the solubility of the active substance would have been obvious over the oxicam actives taught by Nemoto (Page 1, claim 1).

Regarding instant claims 75-79, the limitation of an excipient would have been obvious over the calcium hydrogen phosphate taught by Nemoto (Page 6, Embodiment 9).

Regarding instant claim 80, the limitation of the particle size of the filler would have been obvious over the calcium hydrogen phosphate taught by Nemoto (Page 6, Embodiment 9). One with ordinary skill in the art would modify the particle size of the filler during the process of routine optimization and the recited particle size (140 μm) would have been an obvious variant unless there is evidence of criticality or unexpected results.

Regarding instant claims 82-83, 95-96 and 108, the antacid would have been obvious over the sodium hydrogen carbonate and calcium hydrogen phosphate disclosed by Nemoto (Page 1, claim 3). The limitation of the mean particle size of the antacid-like substance would have been obvious because one with ordinary skill in the art would vary the particle size of the antacid during the process of routine experimentation depending on the desired attributes of the composition and over the final particle size of granules from about 200 to about 400 microns, as taught by Bhardwaj (Col. 6, claim 1, lines 11-24). The recited particle size (at the most 297 μm) would have been an obvious variant unless there is evidence of criticality or unexpected results.

Regarding instant claims 85-86, the active substance would have been obvious over the piroxicam and tenoxicam disclosed by Nemoto (Page 2, 3rd paragraph).

Regarding instant claims 91-92, the dosage of the active substance would have been obvious over the 2mg of chlortenoxicam and tenoxicam disclosed by Nemoto (Page 5, Table 1).

Regarding instant claim 109, the dissolution test would have would have been obvious over the artificial gastric juice (with an acidic pH) taught by Nemoto (Page 9, Table 3). A person skilled in the art would have found it obvious to test the dissolution/release of the active at various pH levels (especially acidic pH levels which are present in gastric conditions) during the process of routine optimization to ensure the release of the active ingredient.

Regarding instant claim 111, the coated tablet would have been obvious over the coating of tablets taught by Nemoto (Page 4, 2nd full paragraph).

Regarding instant claims 125-126, the limitations of the granulate would have been obvious over the granules of the antacid and oxicam antiinflammatory drug taught by Nemoto (Page 3).

9. Claims 87-90, 93-94 and 115-120 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Nemoto et al. (JP 03-240729) in view of Bhardwaj et al. (US 5,578,316), Melia et al. (Aliment. Pharmacol. Therap. (1989) 3, 513-525) and Penkler et al. (US 5,854,226).

The teachings of Nemoto, Bhardwaj and Melia are stated above.

Nemoto, Bhardwaj and Melia do not expressly teach lornoxicam as the active substance.

Penkler teaches a pharmaceutical composition for oral administration comprising an inclusion complex of a non-steroidal anti-inflammatory drug, including lornoxicam (Col. 5, lines 66-67), an alkaline earth metal bicarbonate, and further active ingredients (Abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make an oral solid preparation containing one or more types of antacids that accelerates the absorption of oxicam antiinflammatory drugs, as suggested by Nemoto, combine it with the pharmaceutical granule composition for oral administration where the final particle size of the granule is from about 200 to about 400

microns, as taught by Bhardwaj, further combine it with a lornoxicam and alkaline earth metal bicarbonate containing composition, as suggested by Penkler, and produce the instant invention.

One of ordinary skill in the art would do this because the use of lornoxicam in a pharmaceutical composition with an alkaline earth metal bicarbonate is known, as evidenced by Nemoto and Penkler. One with ordinary skill in the art would find it obvious to substitute lornoxicam for the oxicams used by Nemoto during the process of routine experimentation with a reasonable expectation of success in producing a functional pharmaceutical composition comprising lornoxicam and an alkaline earth metal bicarbonate.

Regarding instant claim 87, the limitation of the lornoxicam would have been obvious over the lornoxicam taught by Penkler (Col. 5, lines 66-67).

Regarding instant claims 88-90, the further active drug substance would have been obvious over the further active drug substance, including paracetamol as taught by Penkler (Col. 8, lines 9-12).

Regarding instant claim 93, the dosage of the active substance would have been obvious over the unit compositions of lornoxicam (4mg) taught by Penkler (Figure 2). One with ordinary skill in the art would vary the dosage of the active ingredient, lornoxicam, in order to optimize the release/dissolution profile, and stability.

Regarding instant claim 94, the water content limitation would have been obvious over the drying step (after the addition of water and mixing steps) as taught by Penkler (Col. 4, line 9). A person skilled in the art would reduce the water content of the

composition in order to improve shelf life and minimize interactions and leaching, therefore, the water content limitation would have been an obvious variant found during routine optimization.

Regarding new claims 115-118, the limitation of lornoxicam would have been obvious over the lornoxicam taught by Penkler (Col. 5, lines 66-67). The limitation of sodium hydrogen carbonate would have been obvious over the sodium hydrogen carbonate disclosed by Nemoto (Page 1, claim 3). The limitation of microcrystalline cellulose would have been obvious over the microcrystalline cellulose disclosed by Nemoto (Page 5, Table 1). The limitation of calcium hydrogen phosphate anhydrous would have been obvious over the calcium hydrogen phosphate disclosed by Nemoto (Page 1, claim 3). The limitations of L-HPC and hydroxy propyl cellulose would have been obvious over the low substituted hydroxypropyl cellulose and the hydroxypropyl cellulose disclosed by Nemoto (Page 5, Table 1). The limitations of water and ethanol would have been obvious over the mixture of alcohol and purified water disclosed by Nemoto (Page 4, lines 5-6). The limitation of calcium stearate would have been obvious over the calcium stearate disclosed by Nemoto (Page 4, line 12).

Regarding new claims 119-120, the limitation of the composition having mechanical strength to enable the composition to be coated using traditional coating equipment would have been obvious over the coating of tablets taught by Nemoto (Page 4, 2nd full paragraph).

10. Claims 121-122 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Nemoto et al. (JP 03-240729) in view of Bhardwaj et al. (US 5,578,316), Melia et al. (Aliment. Pharmacol. Therap. (1989) 3, 513-525) and Olinger et al. (US 5,651,988).

The teachings of Nemoto, Bhardwaj and Melia are stated above.

Nemoto, Bhardwaj and Melia do not expressly teach the crushing strength of the tablets of at least about 50N.

Olinger teaches that the tablet hardness or crushing strength of chewable tablets must be greater than about 30N to be commercially useful (Col. 3, lines 25-35).

Regarding new claims 121-122, the limitation of the composition further comprising a filler having binding properties would have been obvious over the calcium hydrogen phosphate disclosed by Nemoto (Page 1, claim 3). The limitation of the composition comprising the binder in the form of tablets having a diameter of 9.5mm when subjected to a crushing strength test in accordance with Ph. Eur. that has a crushing strength of at least about 50N would have been obvious over the teaching that the hardness or crushing strength of chewable tablets must be greater than about 30N to be commercially useful, as taught by Olinger (Col. 3, lines 25-35).

11. New claims 123-124 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nemoto et al. (JP 03-240729) in view of Bhardwaj et al. (US 5,578,316), Melia et al. (Aliment. Pharmacol. Therap. (1989) 3, 513-525) and Klioze et al. (US 2,887,439).

The teachings of Nemoto, Bhardwaj, and Melia are stated above.

Nemoto, Bhardwaj, and Melia do not expressly teach the composition that passes through a 180 micrometer sieve.

Klioze et al. (US 2,887,439) teach a tablet that may be swallowed whole, chewed, dissolved in the mouth, or dissolved or suspended in liquids (Col. 2, lines 6-12). This rapidly disintegrating tablet comprises a plurality of compressed granules containing sweetening agents and perhaps a filler (Col. 2, lines 13-20). The granules used in the tablets are screened "to insure that they are of an optimum size for the formation of tablets. It has been found that granules ranging from about 20 to 100 mesh (U.S. Sieve Series) are most advantageous in preparing the tablets of this invention" (Col. 2, lines 41-46). 20 mesh corresponds to 0.84mm or 840μm and 100 mesh corresponds to 0.149mm or 149μm (see Page 1544 of Remington's 16th Edition 1980, as provided by Applicant on 09/15/08). Therefore, Klioze teaches the formation of rapidly disintegrating tablets comprising granules that are between 149μm and 840μm, thereby rendering the instant claims with the limitation of the mean particle size of the particles of the particulate composition at the most 250μm obvious to one of ordinary skill in the art.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make an oral solid preparation containing one or more types of antacids that accelerates the absorption of oxicam antiinflammatory drugs, as suggested by Nemoto, combine it with the pharmaceutical granule composition for oral administration where the final particle size of the granule is from about 200 to about 400

microns, as taught by Bhardwaj, further combine it with the granules that are between 149μm and 840μm, as taught by Klioze, and produce the instant invention.

One of ordinary skill in the art would do this because the modification of granule particle size would have been obvious during the process of routine experimentation, as evidenced by the surface area increase and consequently, the dissolution rate increase, as evidenced by Melia.

Regarding instant claims 123-124, the limitation of the composition that passes through a 180 micrometer sieve would have been obvious over the granules that are between 149μm and 840μm, as taught by Klioze (Col. 2, lines 41-46).

Conclusion

12. No claims are allowed.

13. Since this new rejection was necessitated by applicant's amendment, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615